

AUG - 9 2004

K041492

510(k) SUMMARY

Astra Tech Implants Dental System Immediate Function

Submitters Information

Submitter's Name: Astra Tech, Inc.

Submitter's Address: (US Representative)
Astra Tech Inc.
890 Winter Street, Suite 310
Waltham, MA 02451-1493
781-890-6800 phone
781-890-6808 fax

Contact's names and Telephone numbers: Niklas Lidskog, President, 781-890-6800
Ann-Mari Eriksson, Manager Regulatory Affairs
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Bruce Manning, Consultant, New England
Biomedical Research, 508-393-3100

Date Prepared: May 2004

Address (Manufacturer) Astra Tech AB
P.O Box 14
SE-431-21 Mölndal
Sweden

Device name

Proprietary name: Astra Tech Implants-Dental System, Immediate
function

Common name: Dental implant

Classification name: Endosseous Dental Implant

Identification of legally market device

Various Brånemark System Dental Implant products, submitted by Nobel BioCare under 510(k) K022562

Description of Device

The Astra Tech Dental Implants are root-formed threaded screws made from commercially pure titanium.

The indications and use for the components are not different from similar components of the predicate device.

Intended Use

This application provides for revision of Astra Tech Dental Implants labeling allowing the option of immediate function.

The intended use for this device is to provide support for prosthetic constructions for fully and partially edentulous arches using one or two stage surgical procedures.

Indications for use

The Astra Tech Implants - Dental System are for single-stage or two-stage surgical procedures and cement or screw retained restorations. The Astra Tech Implants - Dental System are intended for immediate placement and function on single tooth and/or multiple tooth applications recognizing sufficient bone stability (type I or II bone) and appropriate occlusal loading, to restore chewing function. Multiple tooth applications may be splinted with a bar.

Comparison of technological characteristics.

The technological characteristics of the Astra Tech Dental Implants remain unchanged. This application does only provide for a change in labeling allowing the option of immediate function.

Substantial equivalence of the Astra Tech Dental Implants is based on design similarities between the predicate device and the device in this application. The proposed and the predicate device are very similar in terms of material, size and basic design.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG - 9 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Astra Tech, Incorporated
C/O Mr. Bruce R. Manning
New England Biomedical Research, Incorporated
96 West Main Street
P.O. Box 809
Northborough, Massachusetts 01532

Re: K041492
Trade/Device Name: Astra Tech Implants – Dental System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: II
Product Code: DZE
Dated: June 3, 2004
Received: June 4, 2004

Dear Mr. Manning:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a **substantial equivalence** determination does not mean that FDA has made a determination **that your device** complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Chiu Lin", with a stylized flourish at the end.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041492

Device Name: Astra Tech Implants – Dental System

Indications For Use:

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Prescription Use XX

AND/OR

Over-The-Counter Use

(Part 21 CFR 801 Subpart D)

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Andrew Batz *for Dr. Susan Brunner*

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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